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EXAMINER	
CAPUTA, A	
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Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run 4 months or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 10/18/95 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☒ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: see attachment

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

   Claims allowed: none
   Claims objected to: none
   Claims rejected: 1, 4, 5, 7, 8, 12, 17 and 19-21

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because see attachment

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

ADVISORY ACTION

1. The amendment filed October 18, 1995 (Paper No. 23) under 37 C.F.R. § 1.116 in response to the final rejection has been considered but will not be entered because:

1. it raises new issues that would require a further consideration and search

2. they are not deemed to place the application in a better form for appeal by materially reducing or simplifying the issues for appeal, and

3. additional claims are presented without cancelling a corresponding number of finally rejected claims.

The after final amendment as proposed by applicants will not be entered, since newly added claims 22 and 23 would require further consideration under 112, second paragraph for lack of antecedent basis for the term "polynucleotide" since the independent claims as proposed by applicants claim "polynucleotides" and not "polynucleotide".

Further the amendment after final will not entered since the scope of the claimed invention has been changed from

a nucleic acid comprising polynucleotides coding for the surface proteins HA and NA of a selected wild type influenza virus and polynucleotide which codes for PB2 which consists of the sequence as recited

to a nucleic acid which further comprises PB1, PA and M of a cold adapted virus (see amended claims 8 and 12 and dependent claims thereof).

It is the Examiner position that by changing the scope of the claimed nucleic acid the proposed amendment would require a further search of polynucelotides coding for PB1, PA and M of a cold adapted virus. Furthermore, by changing the scope of the claimed nucleic acid to encompass polynucelotides coding for PB1, PA and M of a cold adapted virus as claimed would require further consideration under 35 USC 112, first paragraph. It is the Examiner's position the specification fails to provide an

enabling disclosure of how to make polynucleotides coding PB1, PA, and M proteins of a cold adapted virus, particularly since the specification fails to provide sufficient guidance of which nucleotide sequences of the PB1, PA, and M proteins provide a cold adapted phenotype as claimed.

2. Applicants' copies of the abstract of Herlocher et al., abstract of Castrucci, Kilbourne article, and article by WHO listed in the information disclosure statement (IDS) dated March 18, 1994 which were inadverently omitted by applicants (see Applicants' Communication dated 7/3/95; Paper No. 21), and the full text article of Castrucci and Herlocher et al. and additional pages 333-345 of the Kilbourne article which were not listed in said IDS were not considered. The information disclosure statement fails to comply with 37 CFR § 1.97(d) because it lacks either a certification as specified in 37 CFR § 1.97(e), a petition requesting consideration of the information disclosure statement, and/or the petition fee set forth in 37 CFR § 1.17(i)(1). It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

3. The prior objection to the disclosure is maintained as set forth in the last Office Action.

In view that the amendment after final has not been entered for the reasons set forth above, the prior objection to the disclosure is maintained.

4. The prior objection to the specification under 35 U.S.C. § 112, first paragraph, for failing to provide an enabling disclosure is maintained.

In view that the amendment after final has not been entered for the reasons set forth above, the prior objection to the disclosure is maintained, since as exemplified by the prior art

it appears more than the PB2 is required since other genes such as PA, M, and PB1 contribute to attenuation (see Snyder et al., particularly abstract).

However, the Examiner withdraws the objection to the specification of the use of the animal model to predict how to use the claimed invention for vaccination.

5. The prior rejection of claims 12, 17, 19, and 20 under 35 U.S.C. § 112, first paragraph, is maintained for the reasons set forth in the last Office Action.

6. The prior rejection of claims 1, 4, 5, 7, 8, 12, 17, and 19-21 under 35 U.S.C. § 103 as being unpatentable over Cox et al. (Virology 167:554-567 1988) and further in view of Belshe et al. (J. Infectious Disease 149(5): 735-740 May 1984 or Belshe et al. (J. Infectious Disease 165: 727-732 April 1992) is maintained as set forth in the last Office Action.

Applicants argue that since the Cox et al. PB2 gene differs from nucleotides positions 714, 963, and 1933 and the prior art (i.e. Cox et al.) does not suggest the nucleotides at 141, 821, and 1933 the rejection should be withdrawn. While it may be true that there may be difference in the nucleic acid sequence of the PB2 of the prior art and as claimed it is reasonable for one of ordinary skill in the art to expect the that there are an obvious or analogous variant of each other since they appear to have the same functional properties (i.e. both useful for the development of a vaccine, both are comprised of a reassortant which uses the cold adapted mutant as the donor strain and the HA and NA (surface antigens) from an epidemic variant virus).

Since: 1.) applicants have not provided any conclusive evidence that the nucleotide differences taught or suggested by the prior art contribute to functional properties; 2.) the

specification only disclose that the difference of nucleotide position (i.e. nucleotide positions 141 and 1933) may contribute to the cold adapted phenotype (see page 9, lines 34-36), and 3.) applicants have failed to demonstrate the prior art does not have the nucleotide differences as argued [i.e. see Subarro et al. provided by applicants, page 7227; Column 2; who teaches the virus as set forth by Cox et al. has a single amino acid substitution at position 265 which appears to correspond to nucleotide 821} it is the Examiner's position that the rejection is proper.

Mere discovery that claimed composition possesses property not disclosed for prior art does not **alone** defeat prima facie case of obviousness and it is **not** necessary, in order to establish prima facie case, to show both structural similarity between claimed and prior art compound **and** suggestion in, or expectation from, prior art that claimed compound will have same or similar utility as one newly discovered by applicant. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990).

For the reasons set forth above and in the last Office Action said rejection is maintained.

7. The prior rejection of claims 1, 4, 5, 7, 8, 12, 17, and 19-21 under 35 U.S.C. § 112, second paragraph, is maintained as set forth in the last Office Action.

Applicants have amended most of the pending claims to recite consisting. In view that the amendment after final has not been entered for the reasons set forth above, the prior rejection is maintained. Applicants further argue the metes and bounds of the claimed subject matter are clear. However, since the transition phrase "consisting essentially" to further limit a compound (i.e nucleic acid) is used to limit a composition and not a compound, it remains unclear what the metes and bounds of the claimed subject matter.

Anthony C. Caputa
November 22, 1995

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